

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 20 FEB 2006

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Applicant's or agent's file reference GENOM.032VPC	FOR FURTHER ACTION		See Form PCT/IPEA/416
International application No. PCT/US04/27412	International filing date (day/month/year) 23 August 2004 (23.08.2004)	Priority date (day/month/year) 25 August 2003 (25.08.2003)	
International Patent Classification (IPC) or national classification and IPC IPC(8): C12Q 1/68; C12P 19/34 and US Cl.: 435/6, 91.1, 91.2			
Applicant GENEOHM SCIENCES, INC.			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 25 October 2005 (25.10.2005)	Date of completion of this report 01 February 2006 (01.02.2006)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer James Martinell <i>J. Roberts for</i> Telephone No. (571) 272-0719

Form PCT/IPEA/409 (cover sheet)(April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☒ the description:
pages 1-143 _____ as originally filed/furnished
pages* NONE _____ received by this Authority on _____
pages* NONE _____ received by this Authority on _____
- ☒ the claims:
pages 144-180 _____ as originally filed/furnished
pages* NONE _____ as amended (together with any statement) under Article 19
pages* NONE _____ received by this Authority on _____
pages* NONE _____ received by this Authority on _____
- ☒ the drawings:
pages 1-17 _____ as originally filed/furnished
pages* NONE _____ received by this Authority on _____
pages* NONE _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees the applicant has, within the applicable time limit:

- ☐ restricted the claims.
☐ paid additional fees.
☐ paid additional fees under protest, and, where applicable, the protest fee
☐ paid additional fees under protest but the applicable protest fee was not paid
☒ neither restricted the claims nor paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:

- ☐ complied with.
☒ not complied with for the following reasons:

4. Consequently, this report has been established in respect of the following parts of the international application:

- ☐ all parts
☒ the parts relating to claims Nos. 1-48 and 64-152

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Inventive Step (IS)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO
Industrial Applicability (IA)	Claims <u>Please See Continuation Sheet</u>	YES
	Claims <u>Please See Continuation Sheet</u>	NO

2. Citations and Explanations (Rule 70.7)

Claims 1-9, 12, 13, 15, 16, 18, 19, 22-24, 26, 29-37, 39-42, 64-73, 76-83, 95-102, 105-112, 114-119, 122-126, 129-134, 137-141, and 144-150 lack novelty under PCT Article 33(2) as being anticipated by Molecular Staging, Inc. (WO 02/077256). The reference teaches a nucleic acid molecular hybridization method that uses probes that contain two regions that bind to the target. Probes that bind to the target are circularized and amplified via rolling circle amplification. The probes of the reference also contain tags and may contain a promoter for the detection of RNA transcribed from the probe. For example, see Figure 1, the Abstract, page 4, line 32 through page 22, line 10, and claims 1-162. The claims describe no more than the reference. Applicant's argument filed 25 October 2005 (page 2, last full paragraph and page 3, first full paragraph) is not convincing. Applicant asserts that Molecular Staging, Inc. (WO 02/077256) does not teach the use of a sequestering agent. This argument is not convincing in view of the teachings in the reference at, for example, page 11, lines 1-25 and page 13, lines 7-29. The reference uses a sequestering sequence to prevent rolling circle amplification in the absence of target sequences.

Claims 10, 11, 14, 17, 20, 21, 25, 27, 28, 38, 43-48, 74, 75, 84-94, 103, 104, 113, 120, 121, 127, 128, 135, 136, 142, 143, 151, and 152 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the claimed methods.

Claims 1-48 and 64-152 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 10, 11, 14, 17, 20, 21, 25, 27, 28, 38, 43-48, 74, 75, 84-94, 103, 104, 113, 120, 121, 127, 128, 135, 136, 142, 143, 151, and 152

The opinion as to Novelty was negative (No) with respect to claims 1-9, 12, 13, 15, 16, 18, 19, 22-24, 26, 29-37, 39-42, 64-73, 76-83, 95-102, 105-112, 114-119, 122-126, 129-134, 137-141, and 144-150

The opinion as to Inventive Step was positive (Yes) with respect to claims 10, 11, 14, 17, 20, 21, 25, 27, 28, 38, 43-48, 74, 75, 84-94, 103-104, 113, 120, 121, 127, 128, 135, 136, 142, 143, 151, and 152

The opinion as to Inventive Step was negative (NO) with respect to claims 1-9, 12, 13, 15, 16, 18, 19, 22-24, 26, 29-37, 39-42, 64-73, 76-83, 95-102, 105-112, 114-119, 122-126, 129-134, 137-141, and 144-150

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-48 and 64-152

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE